

Gerald McEllistrem, M.D. 10/7/2008
In Re: Viagra Products Liability Litigation

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THE UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

IN RE: MDL CASE NO. 1724

VIAGRA PRODUCTS LIABILITY LITIGATION

RICHARD MARTIN, Case No. 06-CV-1064 (PAM)

Plaintiff,

v.

PFIZER INC.,

Defendant.

DEPOSITION OF

GERALD MCELLISTREM, M.D.

Taken October 7, 2008

Scheduled for 9:00 a.m.

Reported By: Lori Morrow, RPR, CRR, CLR
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Deposition of GERALD MCELLISTREM, M.D.,

2

taken on the 7th day of October, 2008, commencing at

3

8:45 a.m., at the University of Minnesota, 516

4

Delaware Street SE, Suite 9240, Minneapolis,

5

Minnesota, before Lori Morrow, Registered

6

Professional Reporter, Certified LiveNote Reporter,

7

Certified Realtime Reporter and a Notary Public in

8

and for the State of Minnesota.

9

10

APPEARANCES:

11

On Behalf of the Plaintiff:

12

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(CONTINUED)

25

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Gerald McEllistrem, M.D.

4

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8

OBJECTIONS BY:

9

Mr. Gomez.....19, 20, 26, 51, 55, 58, 67, 68

10

Ms. Leskin.....72

11

EXHIBITS MARKED AND REFERRED TO: PAGE:

12

1 Medical records 13, 33-34

13

2 Label for Viagra in effect as of 2/1999 30-42

14

3 Last 2 medical records; the front page

of Dr. McEllistrem's folder; and the

15

back page of Dr. McEllistrem's folder 39

16

4 One-page note dated 7/29/96 43

17

5 Articles provided by Dr. McEllistrem 63-65

18

6 Article entitled Gorkin, et al.,

Sildenafil Citrate Use and the

19

Incidence of Nonarteritic Anterior

Ischemic Optic Neuropathy 2006 65-66

20

21

7 Article by Dr. McGwin, et al.,

Nonarteritic Anterior Ischemic Optic

Neuropathy and the Treatment of Erectile

22

Dysfunction from the British Journal of

Ophthalmology 2006 66-68

23

24

8 Viagra label 69-70

25

(REPORTER'S NOTE: Original Exhibits are

attached to the original transcript.)

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1

APPEARANCES (CONTINUED):

2

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NOTE: The original transcript will be

delivered to Lori B. Leskin, Esquire, pursuant to

9

the applicable Rules of Civil Procedure.

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Page 5

1

GERALD MCELLISTREM, M.D.,

2

duly sworn, was examined and testified as follows:

3

EXAMINATION

4

BY MS. LESKIN:

5

Q Good morning, Doctor. How are you?

6

A Good. Thank you.

7

Q You understand you're not being sued in

8

this litigation, right?

9

A I do.

10

Q Okay. We're just here to get some

11

information about your care and treatment of

12

Mr. Martin.

13

A Right.

14

Q Right? Okay. As I intro duced myself a

15

few minutes ago, my name is Lori Leskin, and with me

16

is Avigael Fyman. We represent Pfizer in this

17

matter.

18

A Okay.

19

Q You and I have never met before, correct?

20

A That's correct.

21

Q And we've never spoken, right?

22

A That's true.

23

Q Have you spoken with anyone on behalf of

24

Pfizer about this litigation?

25

A No, I have not.

2 (Pages 2 to 5)

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<p>1 Q Have you spoken to Mr. Martin about this 2 litigation? 3 A I have not. 4 Q Have you spoken to any of Mr. Martin's 5 lawyers? 6 A No, I have not. 7 Q Have you ever been deposed before? 8 A Yes. Years ago. 9 Q How many times? 10 A Once. 11 Q And was that in connection with a lawsuit 12 against you? 13 A No. That was a lawsuit against -- gosh, 14 it was 30 years ago. It was about a kidney stone 15 and whether the guy could work with a kidney stone. 16 Q And were you a fact witness or an expert 17 witness in that case? 18 A I was both. 19 Q Okay. Since it's been so long, and I know 20 you're represented here by counsel, I'm just going 21 to go over a couple of the ground rules of the 22 deposition so we're all on the same page. Okay? 23 A Okay. 24 Q The court reporter is taking down 25 everything that's being said today. So it's very</p>	<p>1 Q Can you give me a little bit about your 2 educational background starting with college 3 education? 4 A College, St. Thomas College, St. Paul, 5 Minnesota, graduated in 1950; medical school, 6 Creighton, C-R-E-I-G-H-T-O-N, Creighton Medical 7 School, Omaha, Nebraska, finished in 1954; 8 internship, St. Joseph's Hospital, St. Paul, 9 Minnesota, '54 to '55; year of surgery residency, 10 St. Joseph's Hospital, St. Paul, '55 to '56; three 11 years of residency at Regions Hospital in St. Paul 12 from '58 through '61. 13 Q And from '56 to '58, what were you doing? 14 A Oh, that was service time. That was in 15 the service. 16 Q And which armed -- 17 A Navy. Navy. 18 Q And what was your highest rank? 19 A Lieutenant, Senior Grade. 20 Q And were you honorably discharged? 21 A Yes, I was. 22 Q After your residency at Regions Hospital 23 in 1961, what did you do after that? 24 A I went directly into the practice of 25 urology.</p>
Page 7	Page 9
<p>1 important that all of your answers be verbalized. 2 A Okay. 3 Q It's very hard for her to take down a nod 4 of the head or a shrug of the shoulders and get the 5 appropriate meaning in the transcript. Okay? 6 A Okay. 7 Q It's very natural, and a lot of people 8 have a tendency to go "uh-huh" or nod their head. 9 And if you do that, one of the lawyers in this room 10 will correct you. 11 A All right. Fine. 12 Q It's also important that only one of us 13 speak at time. So it's important that you let me 14 finish my question, and I'll let you finish your 15 answer. Okay? 16 A Sounds good. 17 Q If your attorney or Mr. Martin's attorney 18 raises any objection, let them put their objection 19 on the record, and then your attorney will direct 20 you whether or not to continue and go ahead and 21 answer the question. 22 A Okay. 23 Q If you need a break, just let me know. 24 Okay? 25 A I will.</p>	<p>1 Q And where did you set up your practice? 2 A Practice of urology, St. Paul, Minnesota. 3 Q And were you there through your entire 4 career? 5 A Yes, I was there, uh-huh. 6 Q And I understand you retired this year? 7 A I did. 8 Q Any particular reason? 9 A Age. 10 Q And it was May of this year did I see the 11 letter? 12 A I'm sorry. 13 Q In May of this year you retired? 14 A May of this year, that's correct. 15 Q Did you have a particular specialization 16 in the field of urology? 17 A No. It was general urology. 18 Q And you did surgery? 19 A Correct. 20 Q Did you ever teach? 21 A Not connected formally with any program 22 like university. I just -- I did have residents 23 occasionally, but that was all informal. 24 Q Did you ever do any research sponsored by 25 any pharmaceutical company?</p>

3 (Pages 6 to 9)

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<p>1 A I did not.</p> <p>2 Q Did you ever do any research on your own?</p> <p>3 A No, I did not.</p> <p>4 Q Did you ever do any type of work for any</p> <p>5 type of pharmaceutical company?</p> <p>6 A Never did.</p> <p>7 Q Do you have any published articles?</p> <p>8 A Yes. I have one published article.</p> <p>9 Q And what was that on?</p> <p>10 A It was about adrenal carcinoma.</p> <p>11 Q And when was that published?</p> <p>12 A Oh, gosh. That had to be in the</p> <p>13 late '60s.</p> <p>14 Q And where was it published?</p> <p>15 A One of the journals. I think it was the</p> <p>16 Journal -- I'm not sure. I think it was the Journal</p> <p>17 of Urology, but I'm not absolutely certain of that.</p> <p>18 Q And what was the nature of the article?</p> <p>19 A Just how to diagnose adrenal cancer and</p> <p>20 how to treat it.</p> <p>21 Q During the time that you were in practice,</p> <p>22 were you always in the same office?</p> <p>23 A I stayed in the same office. Well, moved</p> <p>24 around a little bit from office to office but in the</p> <p>25 same city, St. Paul.</p>	<p>1 Q And when you retired, what did you do with</p> <p>2 your records for your patients?</p> <p>3 A Brought them home.</p> <p>4 Q And you still have those at home?</p> <p>5 A I do.</p> <p>6 Q While you were practicing, was it</p> <p>7 important for you to keep accurate records of your</p> <p>8 patients?</p> <p>9 A Yes, it was.</p> <p>10 Q And when you wrote notes of your visits</p> <p>11 with your patients, did you do that at or about the</p> <p>12 time the patient was in your office?</p> <p>13 A Always took notes while I was talking to</p> <p>14 the patient and then dictated the note after I saw</p> <p>15 the patient.</p> <p>16 Q And what would you do with the written</p> <p>17 notes you had made?</p> <p>18 A Oh, those would just be disposed of.</p> <p>19 Q But the relevant information would all be</p> <p>20 reflected in the dictated note?</p> <p>21 A Correct.</p> <p>22 Q And you did that soon after the patient</p> <p>23 left your office?</p> <p>24 A Did that before the patient left the</p> <p>25 office -- well, about the time the patient left the</p>
Page 11	Page 13
<p>1 Q And when you moved from office to office,</p> <p>2 you took your medical records for your patients with</p> <p>3 you?</p> <p>4 A I did, yeah.</p> <p>5 Q And did you maintain written copies of all</p> <p>6 of your medical records for your patients?</p> <p>7 A Yes, I did.</p> <p>8 Q Did you ever maintain any separate</p> <p>9 electronic files for your patients?</p> <p>10 A No. I never did get a lot of electronics.</p> <p>11 Q And did you keep those records in the</p> <p>12 ordinary course of business?</p> <p>13 A I always kept the records. We do sort</p> <p>14 through them after 10 years and dispose of records</p> <p>15 that are 10 years or -- that are over 10 years old.</p> <p>16 Q When you dispose of records, is it any</p> <p>17 record that's over 10 years, or just any patient</p> <p>18 that you haven't seen in 10 years?</p> <p>19 A It's any patient that we haven't seen for</p> <p>20 10 years.</p> <p>21 Q Okay. So if you've seen a patient for a</p> <p>22 15-year period, you would keep all of those records</p> <p>23 until you no longer saw the patient?</p> <p>24 A Until he hasn't come back for 10 years,</p> <p>25 right.</p>	<p>1 office.</p> <p>2 Q But that's generally about the same day --</p> <p>3 A Right after -- immediately after each</p> <p>4 patient visit.</p> <p>5 Q And it was important for you in order to</p> <p>6 adequately care for your patients to maintain a</p> <p>7 complete and accurate set of medical records, right?</p> <p>8 A That's correct.</p> <p>9 Q Do you agree that it's important for a</p> <p>10 patient to provide you with accurate information in</p> <p>11 order to allow you to care for your patients?</p> <p>12 A Yes, I do.</p> <p>13 Q And you rely on the accuracy of the</p> <p>14 information your patients provide you, correct?</p> <p>15 A I do.</p> <p>16 (Deposition Exhibit Number 1 was</p> <p>17 Marked for identification and is</p> <p>18 Attached herewith.)</p> <p>19 BY MS. LESKIN:</p> <p>20 Q I've handed you what we've marked as</p> <p>21 McEllistrem Exhibit 1, what was represented to us to</p> <p>22 be a complete set of medical records from your</p> <p>23 office for Richard Martin. I'll ask you to take a</p> <p>24 brief look through them and tell me if there's</p> <p>25 anything you can tell is missing from these records.</p>

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<p>1 A (Perusing documents.) Well, it looks 2 complete. Yes, I think it's complete. I don't see 3 anything missing. 4 Q Now, you brought with you today, it looks 5 like, two manila files? 6 A I did. 7 Q And what are those files? 8 A Well, one is his patient chart. 9 Q Mr. Martin's? 10 A Of Mr. Richard Martin. And the other is 11 copies of Mr. Richard Martin's chart, although 12 slightly incomplete, and also some articles on 13 Viagra and associated blindness. 14 Q And how did that second chart come to 15 exist? 16 A I just produced it. 17 Q Okay. And when did you put that together? 18 A Oh, just gradually over -- ever since I 19 heard of the case being initiated and that I had to 20 be deposed, I started assembling a couple of 21 articles. And then I thought I would get a separate 22 copy of the important features related to Viagra so 23 that if I lost the first chart, I would have backup. 24 Q Okay. And we'll go through your folder 25 that you created for the deposition in a little bit.</p>	<p>1 visit in your files? 2 A I'm going to look. 3 Q It may be that the records were requested 4 before that visit with Mr. Martin. So I just want 5 to make sure that there's nothing after the request. 6 A There is a record in his chart that I 7 guess is not in this chart on that 4/8/08. 8 Q Okay. Prior to 4/8/08, when was the prior 9 visit with Mr. Martin? 10 A 10/12/07. 11 Q Which I also think is not in Exhibit 1. 12 A I'm sorry? 13 Q I don't believe that note is in Exhibit 1 14 either on that visit. 15 A Okay. So then that whole sheet was not 16 transmitted to you. 17 Q Yeah. It's likely that it didn't exist at 18 the time we requested the records. Are there any 19 other notes in your records subsequent to, I guess, 20 April 27, 2007, which is the latest record in 21 Exhibit 1? 22 A I'm sorry. Run that by me again. 23 Q Sure. The latest record in Exhibit 1, if 24 you look on the top of the page, is April 27, 2007. 25 A Oh, yeah.</p>
Page 15	Page 17
<p>1 The medical record chart, that's the copy that you 2 maintain at your house now that you've retired? 3 A Yes, it is. 4 Q And is that in all aspects identical to 5 what we've marked as Exhibit 1? 6 A Yes, it is. 7 Q Okay. So there's no records in that chart 8 that don't appear in Exhibit 1? 9 A I don't think so. I mean, I don't believe 10 so. I mean, there might be some billing sheets that 11 I didn't include, but billing records and signatures 12 for HIPAA is that sort of thing. But outside of 13 that, all the pertinent material should be there -- 14 should be the same -- identical. 15 Q And as we go through it, if there's 16 anything additional in your records that is not in 17 Exhibit 1, we'll make a note of that. 18 A Sure. 19 Q What was the last date that you saw 20 Mr. Martin as a patient? 21 A 4/8/08, 4/8/2008. 22 Q And if you can look at Exhibit 1, do you 23 see a copy of that note in that exhibit? 24 A I don't see it in Exhibit 1. 25 Q Do you have a copy of your notes from that</p>	<p>1 Q And you'll see, if you look on the top of 2 the exhibit, there's a fax line dated May 9, 2007, 3 which is likely when the records were transmitted to 4 us. 5 A Okay. 6 Q Do you have any records in your file that 7 post date April 27, 2007, other than the two visits 8 we just spoke about? 9 A I don't know. I'm hoping I don't. 10 There's one lab test in March of '08, 3/28/08, a 11 laboratory test that probably is not there, and 12 4/17/07, a consult. Oh, that would be in the -- 13 that would be there. I believe that would be the 14 only -- 15 Q Can I see copies of the later documents 16 then? 17 A Yes. 18 Q And maybe we can make a -- have a copy 19 made of those while we're here. 20 A These two. 21 Q Is there anything else in the file there 22 that is relevant to Mr. Martin's care? The front 23 part of the folder there, you have some pages. Are 24 those also post dated April 27, 2007? 25 A The front part of this chart now is the</p>

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Page 18	<p>1 older part of the record of the --</p> <p>2 Q Okay.</p> <p>3 A So this is -- these do have copies of --</p> <p>4 Q And the notes on the front cover of your</p> <p>5 chart --</p> <p>6 A Of the folder?</p> <p>7 Q Of the folder, I notice you have some</p> <p>8 notes written there.</p> <p>9 A Yeah, I do.</p> <p>10 Q What notes are those?</p> <p>11 A Those are the significant procedural notes</p> <p>12 that were summarized so that I can quickly review</p> <p>13 his chart when he comes in and recall at a glance</p> <p>14 what I've done in the past.</p> <p>15 Q And you write those notes at about the</p> <p>16 time that it's occurring?</p> <p>17 A At the time of the procedure.</p> <p>18 Q Okay. Can I make a copy of that front</p> <p>19 page as well?</p> <p>20 A Of this you mean?</p> <p>21 Q Yes, of the folder, of the manila folder.</p> <p>22 A Sure. It's right here.</p> <p>23 Q Okay. And while she's doing that, we'll</p> <p>24 talk about some things other than the medical</p> <p>25 records.</p>	Page 20	<p>1 well. And medication causes are part of it, and</p> <p>2 psychogenic -- there are some psychogenic causes,</p> <p>3 too, of erectile dysfunction.</p> <p>4 Q Focusing on the vascular causes for a</p> <p>5 moment, what are some of the risk factors that men</p> <p>6 have that would lead them to have erectile</p> <p>7 dysfunction or could lead them to have erectile</p> <p>8 dysfunction?</p> <p>9 A Risk factors are hypertension, vascular --</p> <p>10 arteriosclerosis generalized, certainly history of</p> <p>11 smoking and diabetes, of course, affecting the</p> <p>12 vascular tree, and, of course, the medications that</p> <p>13 are used for hypertension.</p> <p>14 Q And the vascular causes that you</p> <p>15 mentioned, they cause erectile dysfunction how?</p> <p>16 A By decreasing blood supply to the corpora</p> <p>17 of the penis and decreasing inflow and causing poor</p> <p>18 circulation to it.</p> <p>19 Q Are men who have erectile dysfunction at</p> <p>20 risk for other types of vascular diseases as well?</p> <p>21 A Oh, yes. There --</p> <p>22 MR. GOMEZ: Objection to form.</p> <p>23 THE WITNESS: Pardon me.</p> <p>24 MR. GOMEZ: I just objected to the form,</p> <p>25 Doctor. You can answer.</p>
Page 19	<p>1 A Okay.</p> <p>2 Q In the course of your career as a</p> <p>3 urologist, did you treat men with erectile</p> <p>4 dysfunction?</p> <p>5 A I do.</p> <p>6 Q And over the course of a year, how many</p> <p>7 men with erectile dysfunction would you estimate you</p> <p>8 treated?</p> <p>9 A Well, maybe 10 a week times 50 weeks would</p> <p>10 be 500 a year about. And that might be a little</p> <p>11 generous. It might be a little less than that.</p> <p>12 Q But it did make up a significant part of</p> <p>13 your practice?</p> <p>14 A It did, yeah.</p> <p>15 Q Would you characterize erectile</p> <p>16 dysfunction as a serious disorder?</p> <p>17 A As a which?</p> <p>18 Q A serious disorder?</p> <p>19 A Yes, I do.</p> <p>20 MR. GOMEZ: Objection to form.</p> <p>21 BY MS. LESKIN:</p> <p>22 Q What are some of the causes of erectile</p> <p>23 dysfunction that you're familiar with?</p> <p>24 A Well, the more common causes are vascular</p> <p>25 causes. Certainly, malignant causes are in there as</p>	Page 21	<p>1 THE WITNESS: Oh, yes. They are subject</p> <p>2 to -- and, in fact, that's one of the things we</p> <p>3 do is to check their other lipid profiles so</p> <p>4 that if there is coronary artery disease, we</p> <p>5 can pick that up a little better.</p> <p>6 BY MS. LESKIN:</p> <p>7 Q And help treat some of those other</p> <p>8 conditions?</p> <p>9 A Treat the other conditions, that's true.</p> <p>10 Q I want to go back to prior to 1998.</p> <p>11 A Okay.</p> <p>12 Q What type of treatments did you have</p> <p>13 available to you as a urologist to treat your</p> <p>14 patients with erectile dysfunction?</p> <p>15 A This was prior to '98 did you say?</p> <p>16 Q Yes.</p> <p>17 A The treatments that we had available then</p> <p>18 were various oral medications and certainly more</p> <p>19 invasive types of treatments and mechanical</p> <p>20 treatments. So we had -- the vacuum depression</p> <p>21 device was available to us and then also the</p> <p>22 injectable treatment program for erectile</p> <p>23 dysfunction.</p> <p>24 Q Did you do any surgical implant as well?</p> <p>25 A Yes, I did. But it's been a long time</p>

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<p>1 since I've done them, but I had done surgical 2 implants for that.</p> <p>3 Q You mentioned there were some oral 4 medications. Prior to 1998, what oral medications 5 existed to treat erectile dysfunction?</p> <p>6 A Well, the ones that were most commonly 7 used were Yohimbine, Y-O-H-I-M-B-I-N-E, and 8 Trazodone, T-R-A-Z-O-D-O-N-E. Those two were some 9 of the more useful ones.</p> <p>10 Q Trazodone wasn't a -- strike that. 11 The treatment of erectile dysfunction 12 wasn't an FDA approved indication for Trazodone?</p> <p>13 A It was off label.</p> <p>14 Q It's really an antidepressant?</p> <p>15 A It is, but it has some side effects that 16 we use.</p> <p>17 Q Was it an effective medication for the 18 treatment of erectile dysfunction?</p> <p>19 A Periodically. It had an incomplete 20 record, and, certainly, it was superseded by the 21 newer medications available.</p> <p>22 Q And what about Yohimbine?</p> <p>23 A Yohimbine was somewhat the same. It 24 worked a little differently and sometimes helped. 25 But commonly, on a severer case of ED, it would not</p>	<p>1 A Well, MUSE was the -- that came a little 2 later, I think. And that was a suppository -- a 3 intra-urethral suppository that was the same 4 medication used in Caverject. But I don't know that 5 was available in pre-1998. It might have been, but 6 I'm not certain that it was.</p> <p>7 Q Okay. The Caverject was an actual needle?</p> <p>8 A It was a needle, uh-huh.</p> <p>9 Q And that was injected into the penis, 10 right?</p> <p>11 A Into the corpora, into the blood bodies, 12 right.</p> <p>13 Q And what were your patients' reactions to 14 the Caverject?</p> <p>15 A Well, it was very successful. It worked 16 very well. The disadvantage is that, after a period 17 of time, they get tired of using a needle. It was 18 uncomfortable. They disliked it.</p> <p>19 Q And what type of side effects did your 20 patients experience with the Caverject?</p> <p>21 A Biggest side effect was one of discomfort 22 with using it and a little bit of complex 23 preparation of the medication.</p> <p>24 Q And we mentioned MUSE came on a little bit 25 later in -- I think '97 it may have been approved.</p>
Page 23	Page 25
<p>1 be useful.</p> <p>2 Q You mentioned the vacuum compression 3 devices. How did that work?</p> <p>4 A Well, just a cylinder that produces a 5 vacuum around the penis and promotes blood flow into 6 the penis. The compression ring sliding around the 7 cylinder at the base of the penis prevents the blood 8 from leaving the penis and maintains the erection.</p> <p>9 Q Were your patients satisfied with the 10 vacuum compression?</p> <p>11 A Compression device? It's a little 12 uncomfortable, and I suppose I had a success rate 13 with it of somewhat less than 50 percent.</p> <p>14 Q What type of side effects did your 15 patients experience with the vacuum compression 16 device?</p> <p>17 A Pain is the biggest one, uncomfortable 18 from the compression ring both to the patient and to 19 his partner.</p> <p>20 Q You also mentioned injectable treatments.</p> <p>21 A Correct.</p> <p>22 Q Now, I understand there was a treatment 23 called Caverject.</p> <p>24 A Caverject.</p> <p>25 Q And then also one called MUSE?</p>	<p>1 A Yeah.</p> <p>2 Q And as you said, that was a suppository, 3 right?</p> <p>4 A That was an intra-urethral suppository.</p> <p>5 Q And what was your patients' reaction to 6 the MUSE?</p> <p>7 A MUSE, I think, was not quite as well 8 accepted as the Caverject simply because it caused 9 discomfort. It was an irritant to the urethral 10 mucosa, and it was painful for the patients, and it 11 was not as effective as Caverject.</p> <p>12 Q And you also said you did some implants, 13 correct?</p> <p>14 A Uh-huh.</p> <p>15 Q Yes?</p> <p>16 A Yes, I did.</p> <p>17 Q And that's a pretty severe intervention, 18 correct?</p> <p>19 A Yes, that is.</p> <p>20 Q When did you first start prescribing 21 Viagra to your patients -- well, let me strike that. 22 When Viagra came on the market, did you, 23 in fact, prescribe it to your patients?</p> <p>24 A I did.</p> <p>25 Q And when did you start prescribing it to</p>

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Page 26	<p>1 your patients?</p> <p>2 A Well, post 1998.</p> <p>3 Q Okay. If it was approved in March of</p> <p>4 1998, how long after approval would you say you</p> <p>5 began prescribing it?</p> <p>6 A Oh, I believe I probably prescribed it</p> <p>7 within six months of its approval.</p> <p>8 Q And did you find it to be an effective</p> <p>9 medication for your patients?</p> <p>10 A I did. It was.</p> <p>11 Q And did you find it to be a reliable</p> <p>12 medication for your patients?</p> <p>13 A It is.</p> <p>14 Q And did you find it to be a well tolerated</p> <p>15 medication for your patients?</p> <p>16 A Yes, I did.</p> <p>17 Q Would you agree that Viagra was a</p> <p>18 significant advancement in the treatment of erectile</p> <p>19 dysfunction?</p> <p>20 A I would.</p> <p>21 MR. GOMEZ: Objection to form.</p> <p>22 BY MS. LESKIN:</p> <p>23 Q Did you review any of the clinical studies</p> <p>24 regarding Viagra?</p> <p>25 A I did. I did review some.</p>	Page 28	<p>1 A I just explained it verbally to them. I</p> <p>2 didn't give them written information.</p> <p>3 Q And what would you explain to your</p> <p>4 patients about Viagra when you first prescribed it</p> <p>5 to them?</p> <p>6 A Well, I described the drug, how it works</p> <p>7 to some degree, and the side effects that they could</p> <p>8 expect from it. It was -- yeah, it was -- not all</p> <p>9 the side effects were known initially.</p> <p>10 Q Okay. So let's start initially. What</p> <p>11 side effects did you discuss with your patients?</p> <p>12 A Well, the visual changes that would be</p> <p>13 present.</p> <p>14 Q The blue/green vision --</p> <p>15 A Blue/green vision.</p> <p>16 Q -- that you mentioned?</p> <p>17 A The fact that it could drop their blood</p> <p>18 pressures too much if they took it with other alpha</p> <p>19 blockers that were used for prosthetic enlargement,</p> <p>20 so that they had to be careful not to use things</p> <p>21 like Doxazosin, which could potentiate the use of</p> <p>22 Viagra.</p> <p>23 Q Any other side effects you discussed with</p> <p>24 your patients?</p> <p>25 A Those were about the ones I can think of</p>
Page 27	<p>1 Q And what did you learn about the efficacy</p> <p>2 of Viagra?</p> <p>3 A Well, it's a very efficacious drug. It's</p> <p>4 not 100 percent efficacious, but it is very helpful,</p> <p>5 and, in less severe cases of erectile dysfunction,</p> <p>6 it works very well.</p> <p>7 Q Was it an improvement over the other oral</p> <p>8 medications that had existed, Trazodone and</p> <p>9 Yohimbine?</p> <p>10 A Yes. In fact, I more or less stopped</p> <p>11 using those drugs when Viagra came on the market.</p> <p>12 Q And what did you learn about -- strike</p> <p>13 that.</p> <p>14 What type of side effects did your</p> <p>15 patients report to you from the Viagra?</p> <p>16 A The biggest side effect was visual, the</p> <p>17 blue lights, green lights that they sometimes saw</p> <p>18 within a couple of hours of using the drug.</p> <p>19 Q And were those permanent visual changes?</p> <p>20 A No. They were temporary.</p> <p>21 Q And did it cause any of your patients to</p> <p>22 stop taking Viagra?</p> <p>23 A No. They took it.</p> <p>24 Q Did you have any written information about</p> <p>25 Viagra that you provided to your patients?</p>	Page 29	<p>1 that I prescribed.</p> <p>2 Q Did you discuss with your patients not to</p> <p>3 take Viagra with nitrates?</p> <p>4 A Oh, yes. I'm sorry. I did. I did, yeah.</p> <p>5 Q And that also -- that was a</p> <p>6 contraindication on the label?</p> <p>7 A That was a contra -- you couldn't use</p> <p>8 Viagra then.</p> <p>9 Q Okay. You said that the side effects</p> <p>10 changed over time. Did there come a time that you</p> <p>11 gave additional information to your patients?</p> <p>12 A Yes, there was a time. And I can't give</p> <p>13 you the exact date, but when it became -- when the</p> <p>14 association between blindness and Viagra was</p> <p>15 reported, then I had to explain to the patients that</p> <p>16 this was a rare occurrence and that there is some</p> <p>17 debate as to whether it's etiologic. But I did</p> <p>18 express that to them, and they understood that.</p> <p>19 Q When you said there's some debate as to</p> <p>20 whether it's etiologic, you mean there's some debate</p> <p>21 as to whether or not Viagra causes the blindness</p> <p>22 that was reported?</p> <p>23 A Exactly.</p> <p>24 Q Did you have any patients who decided not</p> <p>25 to take Viagra after you told them that information?</p>

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<p style="text-align: right;">Page 30</p> <p>1 A That information, yes, I did. 2 Q Okay. How many patients? 3 A Well, I think they were the minority. I 4 would say 10 percent of the patients would not take 5 the drug after they learned of that side effect. 6 Q Did there come a time that you would 7 discuss with patients that there had been reports of 8 men having heart attacks after taking Viagra? 9 A You know, I was not really aware of heart 10 attacks secondary to Viagra. Maybe it's been 11 reported, but I never experienced it, never reported 12 it. 13 Q You told me that you started at some point 14 discussing reports of blindness in patients. When 15 did you start discussing it with your patients? 16 A I think it had to be in the early 2000s. 17 (Deposition Exhibit Number 2 was 18 Marked for identification and is 19 Attached herewith.) 20 BY MS. LESKIN: 21 Q And what was that based on that you had 22 read that caused you to start discussing that with 23 your patients? 24 A Right. There were various articles in the 25 journals that described this and associated journals</p>	<p style="text-align: right;">Page 32</p> <p>1 A I did, uh-huh. 2 Q If you can turn to page 17 of Exhibit 2. 3 A I have it. 4 Q You see there's some information there in 5 the adverse reaction section entitled Post Marketing 6 Experience. 7 A Yes. 8 Q And there's a paragraph there entitled 9 Cardiovascular. 10 A Uh-huh. 11 Q And it says, "Serious cardiovascular 12 events, including myocardial infarction, sudden 13 cardiac death, ventricular arrhythmia, 14 cerebrovascular hemorrhage, transient ischemic 15 attack and hypertension have been reported 16 post-marketing in temporal association with the use 17 of Viagra. Most, but not all, of these patients had 18 preexisting cardiovascular risk factors. Many of 19 these events were reported to occur during or 20 shortly after sexual activity, and a few were 21 reported to occur shortly after the use of Viagra 22 without sexual activity. Others were reported to 23 have occurred hours to days after the use of Viagra 24 and sexual activity. It is not possible to 25 determine whether these events are related directly</p>
<p style="text-align: right;">Page 31</p> <p>1 that pointed out the association between the two, 2 the drug and the blindness. 3 Q We've marked as Exhibit 2 the label for 4 Viagra. And if you look at the back page, you'll 5 see this is the one that was in effect as of 6 February of 1999. 7 A Okay. Let's see. 8 Q The last page. 9 A The last page. Oh, okay. Revised 10 February of '99. Okay. 11 Q For various medications, you know that the 12 labeling information changes over time as more 13 information is learned, correct? 14 A That's correct. 15 Q How do you keep track of the changes to 16 labels for drugs that you would prescribe? 17 A Well, certainly, articles that occur in 18 the literature, and drug representatives help me to 19 ferret that out as well, certainly, peer groups of 20 physicians that express this, and then 21 conventions -- and medical conventions that I go to. 22 Q And you would as part of your practice 23 keep as up to date as possible on changes to the 24 label information on any medications you prescribe. 25 Is that fair to say?</p>	<p style="text-align: right;">Page 33</p> <p>1 to Viagra, to sexual activity, to the patient's 2 underlying cardiovascular disease, to a combination 3 of these factors, or to other factors." 4 A Uh-huh. 5 Q Do you see that? 6 A I did see that. 7 Q Did you ever discuss that with your 8 patients as a matter of course before you prescribed 9 them Viagra? 10 A The only time I discussed something like 11 that was if they were taking nitrates or other alpha 12 blockers that would combine with the Viagra to 13 decrease the blood pressure enough. It was not at 14 all my experience that there was any relationship 15 there. I never -- I didn't get into that. I didn't 16 feel that was relevant. I mean, it's relevant, but 17 I didn't have any experience with any adverse 18 reactions like that. 19 Q Let's talk about Mr. Martin. Turning to 20 Exhibit 1. When did you first see Mr. Martin as a 21 patient? 22 A That was on July 29 of '96. 23 Q And what was the reason that Mr. Martin 24 came to your office? 25 A Came to me for erectile dysfunction. And</p>

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<p>1 so I examined him, and that's when I prescribed 2 Yohimbine and Trazodone for the treatment of it. 3 Q If you can look at the last page of 4 Exhibit 1 that we marked, you'll see the earliest 5 date on there is September 5, '96. 6 A September 5 of '96, that's true. 7 Q You have a note from prior to that date? 8 A Yes. I saw him on July 29 of '96. 9 Q Okay. 10 A And I -- maybe that record is missing, 11 too, huh? 12 Q That's what it looks like. Can I see a 13 copy of the note from your file? At break, we'll 14 make a copy of this page as well if that's possible. 15 A Okay. Sure. 16 Q So you prescribed Trazodone and Yohimbine, 17 correct? 18 A Uh-huh, I did. 19 Q Did you undertake any test to determine 20 the cause of Mr. Martin's erectile dysfunction at 21 that time? 22 A Well, that was the time that we did the 23 initial examination and obtained some blood 24 studies -- or advised him to get blood studies in 25 determining if there's other causes for the erectile</p>	<p>1 Q What type of side effects did he 2 experience? 3 A He noticed some curvature on erection that 4 was disconcerting to him. So he really didn't like 5 using it as much as -- that was in '96 and '97. 6 Although, he did use it in '97, and I think he 7 discontinued it after 1997. 8 Q When Viagra came on the market? 9 A Yes. 10 Q You mentioned that he experienced a 11 curvature to the penis that he noticed on erection. 12 A Uh-huh. 13 Q Was that Peyronie's disease? 14 A Well, it was a, yes, a mild form of 15 Peyronie's disease, yes. 16 Q And had Mr. Martin experienced 17 Peyronie's -- any type of curvature or Peyronie's 18 disease prior to using Caverject? 19 A Didn't express it to me. 20 Q And is that a common side effect from 21 Caverject? 22 A No, it is not, although it can occur. It 23 certainly can. 24 Q Now, according to your notes of 25 September 29, '98, Mr. Martin had come to you and</p>
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<p>1 dysfunction. 2 Q And through the course of your treatment, 3 did you, in fact, determine the cause of 4 Mr. Martin's erectile dysfunction? 5 A I felt it was vascular inflow deficiency. 6 And so that was the working diagnostic cause. 7 Q And did you make a determination as to the 8 cause of the vascular inflow deficiency? 9 A The determination was based on the 10 hypertension, the treatment for the hypertension, 11 and the history of smoking. Those were the 12 etiologies that I ascribed to it. 13 Q What was -- strike that. 14 Was the Yohimbine and Trazodone effective 15 for Mr. Martin? 16 A You know, I never got a real feedback on 17 that. He went to his primary care physician, and I 18 believe it was -- also, he came back to me. And it 19 could not have been too effective, because that's 20 when we elected to put him on Caverject. 21 Q Okay. And so he tried the Caverject? 22 A He did try the Caverject. 23 Q And was the Caverject effective for him? 24 A It was effective, but he had side effects 25 from it, and he didn't like it.</p>	<p>1 was already taking Viagra as of that date, correct? 2 A That is correct. 3 Q And you did not prescribe him the Viagra? 4 A I did not. 5 Q Did you have any discussions with him 6 about Viagra? 7 A You know, I didn't really discuss the side 8 effect profile of Viagra. I felt that was -- the 9 physician who prescribed it obviously did that, and 10 so it wasn't -- it was simply informational for me 11 that he was taking the drug. 12 Q And during the course of your treatment of 13 Mr. Martin, did you ever actually prescribe Viagra 14 for him? 15 A No, I never did. 16 Q And did you ever provide him with any 17 samples of Viagra? 18 A I can't remember, but it's possible. I 19 don't -- I can't say that I did. 20 Q If you had provided him with samples of 21 Viagra, would you make a note of that in your 22 records? 23 A You know, I might not have. I might 24 not -- it's possible I would give that without 25 making a note.</p>

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<p>1 Q But sitting here today, you don't have any</p> <p>2 specific recollection of providing him with any</p> <p>3 samples of Viagra?</p> <p>4 A I don't recall that, no.</p> <p>5 Q And sitting here today, you don't recall</p> <p>6 having any discussions with him about any of the</p> <p>7 risks associated with Viagra?</p> <p>8 A That's correct.</p> <p>9 Q And to your knowledge, did Mr. Martin</p> <p>10 discuss that solely, if at all, with Dr. Ferrara?</p> <p>11 A With the prescribing physician.</p> <p>12 Q And that was Dr. Ferrara?</p> <p>13 A I think it was. I mean, that's my</p> <p>14 recollection.</p> <p>15 Q Did you ever talk to Dr. Ferrara about</p> <p>16 Mr. Martin's use of Viagra?</p> <p>17 A Only after -- I believe I talked -- we did</p> <p>18 talk about it. And that was regarding the time he'd</p> <p>19 developed side effects. And then he expressed the</p> <p>20 fact that he had given the patient Viagra and the</p> <p>21 patient experienced the side effect.</p> <p>22 Q And the side effect you're referring to,</p> <p>23 his --</p> <p>24 A His blindness.</p> <p>25 Q Okay. And we'll get there in just a</p>	<p>1 is the back folder -- the back page of your -- the</p> <p>2 front page of your folder, and I believe the fourth</p> <p>3 page they copied is the back page of your folder,</p> <p>4 which looks to be copies of his insurance card --</p> <p>5 A Yes.</p> <p>6 Q -- and some basic demographic data.</p> <p>7 A Yes, that is true.</p> <p>8 Q Is that accurate?</p> <p>9 A That's accurate.</p> <p>10 Q And if you look at the first page of</p> <p>11 Exhibit 3, which is the note dated 10/12/2007 --</p> <p>12 A Okay.</p> <p>13 Q -- you see you have a note there that he</p> <p>14 has used Cialis in the past but feels he does not</p> <p>15 need this any longer.</p> <p>16 A That's kind of the note I was referring to</p> <p>17 where he --</p> <p>18 Q Okay.</p> <p>19 A -- doesn't use -- and by implication, he</p> <p>20 didn't use Viagra, either.</p> <p>21 Q Did you ever prescribe Mr. Martin Cialis?</p> <p>22 A On one occasion, I refilled a prescription</p> <p>23 for him for Cialis.</p> <p>24 Q And when was that?</p> <p>25 A Let's see. That had to be August 10 of</p>
Page 39	Page 41
<p>1 moment. Prior to the onset of Mr. Martin's</p> <p>2 blindness, his ischemic optic neuropathy, did he</p> <p>3 ever complain to you about any other side effects</p> <p>4 from the Viagra he had experienced?</p> <p>5 A No. He never did express any problems</p> <p>6 with the use of Viagra.</p> <p>7 Q Do you know when Mr. Martin stopped using</p> <p>8 Viagra?</p> <p>9 A I think he stopped sometime in -- I think</p> <p>10 he discontinued its use towards the end of his</p> <p>11 visits with me. I think that would be close to</p> <p>12 2007 -- 2007, somewhere in through there. I believe</p> <p>13 I have a note somewhere that says he no longer feels</p> <p>14 he needs the drug.</p> <p>15 Q Let's go ahead and mark these last three</p> <p>16 pages. I'm going to give you back your original</p> <p>17 folder and notes, and we're going to mark this</p> <p>18 exhibit.</p> <p>19 (Deposition Exhibit Number 3 was</p> <p>20 Marked for identification and is</p> <p>21 Attached herewith.)</p> <p>22 BY MS. LESKIN:</p> <p>23 Q We've marked as Exhibit 3 four pages from</p> <p>24 your notes. You'll see the first two are those last</p> <p>25 two medical records we identified. The third page</p>	<p>1 '07.</p> <p>2 Q And was that in connection with a visit?</p> <p>3 A No. That was simply a phone-in</p> <p>4 prescription request, and we simply agreed to</p> <p>5 prescribe it on one occasion -- well, with refills.</p> <p>6 Q And had you ever prescribed Cialis for</p> <p>7 Mr. Martin prior to August of '07?</p> <p>8 A No, I did not.</p> <p>9 Q Did you ever discuss with Mr. Martin</p> <p>10 Cialis, his use of Cialis?</p> <p>11 A No. He would have been taking -- again,</p> <p>12 his initial prescription for Cialis was given</p> <p>13 elsewhere, and I hadn't -- this was just a refill.</p> <p>14 I didn't discuss Cialis with him.</p> <p>15 Q And do you know how long he had been</p> <p>16 taking Cialis prior to the time that you called in</p> <p>17 the refill?</p> <p>18 A I don't know exactly how long he took it.</p> <p>19 I think he probably took it for at least six months</p> <p>20 or so. But I would -- that's an estimate, and I'm</p> <p>21 not sure if -- I know it was -- I'm not sure who</p> <p>22 prescribed it for him initially, either. Probably</p> <p>23 Dr. Ferrara.</p> <p>24 Q Did you ever prescribe Levitra for</p> <p>25 Mr. Martin?</p>

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Page 42	<p>1 A No, I did not.</p> <p>2 Q Do you know if he ever took Levitra?</p> <p>3 A I'm not aware that he did.</p> <p>4 Q In September of 2006, and if you look on</p> <p>5 Exhibit 1 on page 10, I believe you'll see your note</p> <p>6 from that date.</p> <p>7 A September 2006? Okay. Oh, let's see.</p> <p>8 Q It's at the top of the page.</p> <p>9 A Okay. I've got September 1.</p> <p>10 Q September 21, 2006?</p> <p>11 A September 21, uh-huh.</p> <p>12 Q You'll see under that entry, you have a</p> <p>13 line, "patient has continuing ED which he attributes</p> <p>14 to Viagra."</p> <p>15 A Oh, that. I think that was either a typo</p> <p>16 or a confused thinking at the time.</p> <p>17 Q Okay. Mr. Martin never attributed his ED</p> <p>18 to Viagra?</p> <p>19 A No. No. That's -- I did see that, and I</p> <p>20 did initial it. But it was -- that's an inaccurate</p> <p>21 statement.</p> <p>22 Q But as of September 21, he did continue to</p> <p>23 have erectile dysfunction?</p> <p>24 A Yes, he did.</p> <p>25 Q And you gave him MUSE to try that day?</p>	Page 44	<p>1 MS. MCELLISTREM: 2006.</p> <p>2 BY MS. LESKIN:</p> <p>3 Q 2006, correct. Okay. And did Mr. Martin,</p> <p>4 to your knowledge, ever, in fact, use the MUSE?</p> <p>5 A I don't have any knowledge that he did. I</p> <p>6 rather suspect he did not use it.</p> <p>7 Q Okay.</p> <p>8 A There were never any -- to my knowledge,</p> <p>9 there were no prescription refills for it and</p> <p>10 certainly no notes saying that he did use it.</p> <p>11 Q And looking -- I'm sorry.</p> <p>12 A Go ahead.</p> <p>13 Q Looking at the visit dated October 12,</p> <p>14 2007, on Exhibit 3 that we just referenced before,</p> <p>15 you noted that -- you note he has used Cialis in the</p> <p>16 past but feels he does not need this any longer.</p> <p>17 Was it your understanding that Mr. Martin no longer</p> <p>18 was suffering from erectile dysfunction as of that</p> <p>19 date?</p> <p>20 A That was the impression I was left with,</p> <p>21 yes.</p> <p>22 Q And have you had any discussions with</p> <p>23 Mr. Martin since October 2007 as to whether or not</p> <p>24 he, in fact, still suffers from any erectile</p> <p>25 dysfunction?</p>
Page 43	<p>1 A Oh, I did give him MUSE, yes.</p> <p>2 Q Do you know if he ever used that?</p> <p>3 A I'm not aware that he did.</p> <p>4 MR. GOMEZ: Lori, I'm sorry. Can we just</p> <p>5 take a five-minute break?</p> <p>6 MS. LESKIN: Sure.</p> <p>7 (Break, 9:38 a.m. to 9:44 a.m.)</p> <p>8 (Deposition Exhibit Number 4 was</p> <p>9 Marked for identification and is</p> <p>10 Attached herewith.)</p> <p>11 BY MS. LESKIN:</p> <p>12 Q Back on the record. Just during the</p> <p>13 break, we marked as Exhibit 4 the one-page note</p> <p>14 dated July 29, 1996 from your records.</p> <p>15 A I see that.</p> <p>16 Q Is that, in fact, the page from your first</p> <p>17 visit with Mr. Martin?</p> <p>18 A That's the page that was missing. That's</p> <p>19 true.</p> <p>20 Q Now, I think just before the break, we</p> <p>21 were discussing your prescription of MUSE to</p> <p>22 Mr. Martin to try in September.</p> <p>23 A That's right.</p> <p>24 Q What was that. September of?</p> <p>25 A Oh, when was that?</p>	Page 45	<p>1 A No. We didn't discuss erectile</p> <p>2 dysfunction. To my knowledge, we didn't discuss it</p> <p>3 again after that.</p> <p>4 Q Now, you've mentioned to me that you</p> <p>5 never, in fact, prescribed Viagra to Mr. Martin.</p> <p>6 A That's correct.</p> <p>7 Q What was the nature of your treatment of</p> <p>8 Mr. Martin after those initial visits discussing</p> <p>9 erectile dysfunction?</p> <p>10 A Well, he was treated for multiple things</p> <p>11 after that. He was treated for a prostate nodule</p> <p>12 that we felt, and he was treated for epididymitis,</p> <p>13 and he was treated for a bladder tumor that we</p> <p>14 removed. And he was evaluated on two separate</p> <p>15 occasions with prostate ultrasound and biopsies for</p> <p>16 abnormal finding in the prostate gland itself.</p> <p>17 Q And were those abnormal findings</p> <p>18 cancerous?</p> <p>19 A They were not cancerous.</p> <p>20 Q Okay.</p> <p>21 A They were to rule out cancer, and they</p> <p>22 did.</p> <p>23 Q And you mentioned that at some point you</p> <p>24 learned that Mr. Martin had suffered visual loss,</p> <p>25 correct?</p>

12 (Pages 42 to 45)

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<p>1 A That would be October 29, 2002.</p> <p>2 Q And what -- at the time that you learned</p> <p>3 Mr. Martin had suffered visual loss in October of</p> <p>4 2002, what were you told about the event?</p> <p>5 A Well, that was when he described the use</p> <p>6 of a new antihypertensive, which caused vertigo and</p> <p>7 sudden loss of vision, and was felt to have</p> <p>8 experienced a vascular occlusion to the optic nerve.</p> <p>9 And at that point, he was converted to a different</p> <p>10 antihypertensive. But the blindness at that point</p> <p>11 was permanent.</p> <p>12 Q And that's your note of October 29, 2002,</p> <p>13 correct?</p> <p>14 A That's correct.</p> <p>15 Q And this note is based on information that</p> <p>16 Mr. Martin provided to you?</p> <p>17 A Yes. That was what he said.</p> <p>18 Q And that's what he said to you in October</p> <p>19 of 2002?</p> <p>20 A That's what he said, yes.</p> <p>21 Q Okay. Now, at some point, you wrote, and</p> <p>22 I'll direct your attention to page 30, which is your</p> <p>23 note dated December 23, 2005.</p> <p>24 A Okay.</p> <p>25 Q And you wrote on December 23, 2005,</p>	<p>1 after December of 2005?</p> <p>2 A Probably was after 2005.</p> <p>3 Q After the note of December 2005?</p> <p>4 A Five. Yes.</p> <p>5 Q What do you recall, if anything, about the</p> <p>6 conversation you had with Mr. Martin on December 23,</p> <p>7 2005, specifically regarding his use of Viagra and</p> <p>8 blindness?</p> <p>9 A He reported that belief to me, that his</p> <p>10 strong feeling at that point was that the Viagra</p> <p>11 caused the blindness. I simply recorded it and</p> <p>12 didn't say anything more about it because it was</p> <p>13 history, and I didn't feel there was any virtue in</p> <p>14 discussing it any further.</p> <p>15 Q Did Mr. Martin tell you why he believed</p> <p>16 that Viagra had caused his blindness?</p> <p>17 A Because it was in close proximity to the</p> <p>18 taking of the drug. He took the drug the night</p> <p>19 before, and the next morning he woke up with</p> <p>20 blindness. And that's what made him convinced that</p> <p>21 the Viagra caused the blindness.</p> <p>22 Q And that's what he reported to you in</p> <p>23 December of 2005?</p> <p>24 A That's correct.</p> <p>25 Q Did he provide you any articles or</p>
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<p>1 patient had blindness felt to be a result of using</p> <p>2 Viagra in 2002. This occurred within 24 hours of</p> <p>3 taking Viagra.</p> <p>4 A That's correct.</p> <p>5 Q And Mr. Martin told you that information</p> <p>6 in 2005, correct?</p> <p>7 A Yes, he did. Yeah.</p> <p>8 Q Okay.</p> <p>9 A Yeah.</p> <p>10 Q At the time that he had his vision loss in</p> <p>11 2002, did you discuss with him whether he had used</p> <p>12 Viagra at any point in close temporal relationship</p> <p>13 with the onset of his blindness?</p> <p>14 A I really did not. I knew he was using it</p> <p>15 about four times a month, and we didn't discuss</p> <p>16 the -- he expressed the belief that the new</p> <p>17 antihypertensive caused the blindness, and I simply</p> <p>18 accepted that. I don't think I can enlarge on that</p> <p>19 at all.</p> <p>20 Q Did you talk to any of Mr. Martin's other</p> <p>21 physicians in 2002 about his loss of vision?</p> <p>22 A I think it was sometime after 2002 that I</p> <p>23 talked to Dr. Ferrara about the blindness and the</p> <p>24 Viagra.</p> <p>25 Q Okay. And would that have been before or</p>	<p>1 literature regarding Viagra and blindness at that</p> <p>2 point in time?</p> <p>3 A No, he didn't give me any articles. I</p> <p>4 wasn't aware that he did any research on it at all.</p> <p>5 In fact, he couldn't read, so he couldn't give me --</p> <p>6 Q Did he provide you with any reason other</p> <p>7 than the temporal association as to how he had come</p> <p>8 to believe that it was Viagra that caused his</p> <p>9 blindness?</p> <p>10 A He didn't give me any additional</p> <p>11 information. I think he certainly did discuss it --</p> <p>12 he obviously discussed it with Dr. Ferrara, and I'm</p> <p>13 sure they had discussions back and forth.</p> <p>14 Q And you told me that some point after</p> <p>15 December 23, 2005, you, in fact, spoke to</p> <p>16 Dr. Ferrara about the Viagra?</p> <p>17 A Yes.</p> <p>18 Q And Mr. Martin's vision?</p> <p>19 A Yes, I did.</p> <p>20 Q What do you recall about that</p> <p>21 conversation?</p> <p>22 A The recollection I have of that</p> <p>23 conversation is that Dr. Ferrara called me and told</p> <p>24 me that this is the only patient he's ever had who</p> <p>25 he prescribed Viagra to that developed blindness.</p>

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<p style="text-align: right;">Page 50</p> <p>1 That was the extent of the conversation.</p> <p>2 Q Did Dr. Ferrara tell you whether he</p> <p>3 believed that Viagra had caused Mr. Martin's</p> <p>4 blindness?</p> <p>5 A His implication was that he believed it.</p> <p>6 I mean, he expressed the belief that the Viagra did</p> <p>7 cause the blindness.</p> <p>8 Q Are you familiar with a condition called</p> <p>9 Nonarteritic ischemic optic neuropathy?</p> <p>10 A Yes, I am.</p> <p>11 Q Prior to this case, were you familiar with</p> <p>12 nonarteritic ischemic optic neuropathy?</p> <p>13 A Yes, I was. And that's what we would</p> <p>14 discuss with patients, if they were prescribed</p> <p>15 Viagra, then I would discuss that condition with</p> <p>16 them.</p> <p>17 Q What is your understanding -- strike that.</p> <p>18 You're aware that ischemic optic</p> <p>19 neuropathy existed before Viagra was on the market,</p> <p>20 correct?</p> <p>21 A Yes, that's correct.</p> <p>22 Q And what was your understanding as to the</p> <p>23 risk factors for nonarteritic ischemic optic</p> <p>24 neuropathy?</p> <p>25 A Well --</p>	<p style="text-align: right;">Page 52</p> <p>1 because of those underlying risk factors?</p> <p>2 A Yes, that's true.</p> <p>3 Q You told me earlier about the discussions</p> <p>4 you generally have with your patients about the</p> <p>5 reports of ischemic optic neuropathy in men taking</p> <p>6 Viagra.</p> <p>7 A True.</p> <p>8 Q And I believe you told me that the</p> <p>9 etiology has not been proven?</p> <p>10 A Well, that's -- yes. That's my</p> <p>11 understanding.</p> <p>12 Q Okay. And so let me ask you this. Do you</p> <p>13 have an opinion -- during the course of your</p> <p>14 treatment of Mr. Martin, did you form an opinion to</p> <p>15 a reasonable degree of medical certainty as to</p> <p>16 whether Viagra caused Mr. Martin's visual loss?</p> <p>17 A Well, I think it was a factor -- I mean,</p> <p>18 my opinion would be that it's a factor in the</p> <p>19 causation of his optic neuropathy. He certainly has</p> <p>20 these vascular problems that could lead to optic</p> <p>21 neuropathy, and antihypertensives will cause marked</p> <p>22 lowering of blood pressure at times. But usually,</p> <p>23 that doesn't cause ischemic optic neuropathy by</p> <p>24 itself. There has to be some other precipitating</p> <p>25 etiology as a rule. And that could be the Viagra,</p>
<p style="text-align: right;">Page 51</p> <p>1 MR. GOMEZ: Objection to the answer.</p> <p>2 THE WITNESS: Can I answer it?</p> <p>3 BY MS. LESKIN:</p> <p>4 Q Uh-huh.</p> <p>5 MS. MCELLISTREM: Yes.</p> <p>6 THE WITNESS: Multiple factors. That</p> <p>7 would be usually vasculopathies, people who have</p> <p>8 hypertension, take antihypertensives, people</p> <p>9 who smoke, people who have diabetes, and some</p> <p>10 people who don't have these particular risk</p> <p>11 factors that just have an optic change that is</p> <p>12 more subject to developing blindness.</p> <p>13 BY MS. LESKIN:</p> <p>14 Q Would you agree with me that men who have</p> <p>15 erectile dysfunction are at risk for ischemic optic</p> <p>16 neuropathy because of the underlying medical</p> <p>17 condition?</p> <p>18 A Run that by me again.</p> <p>19 Q Sure. Let me ask it this way. Would you</p> <p>20 agree with me that erectile dysfunction and</p> <p>21 nonarteritic ischemic optic neuropathy share some of</p> <p>22 the same risk factors?</p> <p>23 A Yes, they do.</p> <p>24 Q And men who have erectile dysfunction are</p> <p>25 at risk of developing ischemic optic neuropathy</p>	<p style="text-align: right;">Page 53</p> <p>1 which could combine with the antihypertensive to</p> <p>2 cause decreased blood flow to the optic nerve.</p> <p>3 Q And when you say could cause, do you think</p> <p>4 it's more likely than not that it did cause, or is</p> <p>5 it just possible that it caused?</p> <p>6 A It's a possibility. It certainly is</p> <p>7 not -- I don't think that -- I think you have to --</p> <p>8 I would have to give the patient this information</p> <p>9 and let the patient make the decision as to whether</p> <p>10 he wants to take that risk.</p> <p>11 Q Okay. But focusing on the causation</p> <p>12 question for Mr. Martin, I guess I just want to go</p> <p>13 back to understand, is it your opinion to a</p> <p>14 reasonable degree of medical certainty that Viagra</p> <p>15 caused Mr. Martin's visual loss?</p> <p>16 A Well, I don't think it was the sole cause,</p> <p>17 but I think that it certainly is likely that it</p> <p>18 contributed to the development of the blindness.</p> <p>19 But it certainly wasn't the sole cause.</p> <p>20 Q And what do you base that on?</p> <p>21 A Well, the fact that he took a -- let's</p> <p>22 see. That the Viagra caused, you mean, the</p> <p>23 blindness or --</p> <p>24 Q Yes.</p> <p>25 A -- helped -- contributed in the cause of</p>

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<p>1 the blindness?</p> <p>2 Q Yes.</p> <p>3 A Well, just on the literature review, that</p> <p>4 indicates that Viagra certainly can be contributory</p> <p>5 in producing blindness.</p> <p>6 Q Anything else?</p> <p>7 A That would probably be the biggest reason</p> <p>8 for --</p> <p>9 Q What literature did you review that</p> <p>10 supports your view that Viagra could have</p> <p>11 contributed to Mr. Martin's blindness?</p> <p>12 A Well, several articles that I brought</p> <p>13 along with me if you want those.</p> <p>14 Q Yes, please.</p> <p>15 A These are the copies of the articles.</p> <p>16 Q Okay.</p> <p>17 A And they're difficult to -- if you look at</p> <p>18 that first page on the first article -- on the</p> <p>19 article that you have there --</p> <p>20 Q That's the article by Dr. Fraunfelder,</p> <p>21 Pomeranz, and Egan.</p> <p>22 A Yes.</p> <p>23 Q The editorial entitled nonarteritic</p> <p>24 Anterior Ischemia Optic Neuropathy and --</p> <p>25 A Yes.</p>	<p>1 the first -- the second paragraph, the first -- the</p> <p>2 one that starts on the second column, it says,</p> <p>3 "Despite the above, a well-researched explanation as</p> <p>4 to how sildenafil therapy could cause NAION does not</p> <p>5 exist."</p> <p>6 A That is so true.</p> <p>7 Q And the next paragraph down says, "Until</p> <p>8 an animal model or scientific study reveals a</p> <p>9 biological basis for NAION caused by treatment with</p> <p>10 sildenafil, most of the case reports of NAION</p> <p>11 related to this drug may be an expected coincidence</p> <p>12 as sildenafil is a top-selling medication and</p> <p>13 patients who receive this drug are frequently older,</p> <p>14 vasculopathic, and already at risk for NAION."</p> <p>15 A That's correct.</p> <p>16 Q Okay. And you agree with that as well,</p> <p>17 correct?</p> <p>18 A I do. I do. You might, though, also</p> <p>19 refer to the article that is labeled a circle with a</p> <p>20 circled three. The second -- the third article</p> <p>21 down.</p> <p>22 Q That's the paper by Sidney Wolfe?</p> <p>23 A Yes.</p> <p>24 Q There have been inadequate warnings that</p> <p>25 erectile dysfunction drugs can cause blindness?</p>
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<p>1 Q -- Sildenafil?</p> <p>2 A Yes. And you'll see there on the top of</p> <p>3 the second column, there's a sentence that says,</p> <p>4 "Hayreh and others suggest that nocturnal arterial</p> <p>5 hypotension may play a role in ischemic optic</p> <p>6 neuropathy. Patients who are vasculopathic and</p> <p>7 taking hypotensive medications, i.e. blood pressure</p> <p>8 medications or phosphodiesterase inhibitors such as</p> <p>9 sildenafil may be at increased risk for NAION due to</p> <p>10 nocturnal hypotension." So that's probably one of</p> <p>11 the -- however, if you look at the first column</p> <p>12 down, on the second paragraph, where it says about</p> <p>13 four lines down, it says, "However, this</p> <p>14 classification also allows that a concurrent disease</p> <p>15 or the ingestion of other drugs or chemicals could</p> <p>16 cause NAION. I shouldn't say also, but could cause</p> <p>17 NAION." So there was an association between</p> <p>18 sildenafil and NAION as possible according to the</p> <p>19 World Health Organization criteria.</p> <p>20 Q And that's to be distinguished from</p> <p>21 probable, correct?</p> <p>22 MR. GOMEZ: Objection to form.</p> <p>23 THE WITNESS: That's true.</p> <p>24 BY MS. LESKIN:</p> <p>25 Q And if you look at the right-hand column,</p>	<p>1 A Yes.</p> <p>2 Q Okay.</p> <p>3 A And the second paragraph down they did --</p> <p>4 for Viagra there -- approximately -- well, perhaps</p> <p>5 before I get to that, you have to say to test this</p> <p>6 thesis that Viagra could cause NAION, they checked a</p> <p>7 million prescriptions filled, comparing them with</p> <p>8 Lipitor for the same class of individual compared to</p> <p>9 Viagra. And for Viagra, there were 18 times more</p> <p>10 reports of NAION per million prescriptions than for</p> <p>11 Lipitor, and for Cialis 25 times more reports. The</p> <p>12 other one that is noteworthy is that further</p> <p>13 evidence of causation can be seen in a case report</p> <p>14 in which one patient using Cialis suffered</p> <p>15 reversible visual field defects within two hours</p> <p>16 after taking four sequential diagnoses of Cialis and</p> <p>17 suffered permanent loss of vision shortly after the</p> <p>18 fifth dose.</p> <p>19 Q You'll see the note further down that</p> <p>20 paragraph that Dr. Pomeranz joined in Dr. Wolfe's</p> <p>21 petition to the FDA to change the labeling for these</p> <p>22 medications, correct? Do you see that note?</p> <p>23 A Let's see. Where do you see that?</p> <p>24 Q Further down the paragraph.</p> <p>25 A Oh, has joined in the petition, yes.</p>

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Page 58	<p>1 Rapid response is -- okay.</p> <p>2 Q Do you know who Dr. Pomeranz is?</p> <p>3 A I honestly don't.</p> <p>4 Q You'll see he's also a co-author on that</p> <p>5 first article you referred us to --</p> <p>6 A Yes.</p> <p>7 Q -- with Dr. Fraunfelder.</p> <p>8 A Yes.</p> <p>9 Q Do you see that?</p> <p>10 A I do see that, yes.</p> <p>11 Q Are you aware that Dr. Pomeranz has</p> <p>12 testified in this litigation?</p> <p>13 A I was not aware of that.</p> <p>14 Q Are you aware that Dr. Pomeranz said that</p> <p>15 it's not his opinion that Viagra can cause NAION?</p> <p>16 MR. GOMEZ: Objection.</p> <p>17 THE WITNESS: Oh, I was not aware of that.</p> <p>18 BY MS. LESKIN:</p> <p>19 Q Does that affect your opinion?</p> <p>20 A I don't think it changes this article that</p> <p>21 is reported. I think this is a pretty objective</p> <p>22 article that -- his opinion is certainly his</p> <p>23 opinion. But I wouldn't -- it doesn't officiate</p> <p>24 this article.</p> <p>25 Q Have you looked at any of the clinical</p>	Page 60	<p>1 patients have taken Viagra?</p> <p>2 A Well, these were reported in this article,</p> <p>3 the Journal of Ophthalmology reported on PDE5</p> <p>4 inhibitors that do increase the nitric oxide of the</p> <p>5 eye and reduces the blood flow to the optic nerve.</p> <p>6 Q Which article is that?</p> <p>7 A Let's see if I can find that note. I</p> <p>8 think that would be article number 4, Viagra Surgery</p> <p>9 Anesthesia Dangerous Cocktail with Risk of</p> <p>10 Blindness.</p> <p>11 Q That's the article by Fodale?</p> <p>12 A Fodale, De Pietro and Santamaria. It has</p> <p>13 been theorized that sildenafil works through the</p> <p>14 nitric oxide cyclic GMP pathway. May alter the</p> <p>15 perfusion of the optic nerve head by modifying</p> <p>16 nitric oxide levels. In fact, the drug increases</p> <p>17 nitric oxide levels, which, in turn, cause reduced</p> <p>18 perfusion. He makes reference to a Journal of</p> <p>19 Ophthalmology in 2006.</p> <p>20 Q And that's a paper by McGwin, correct?</p> <p>21 A McGwin, correct.</p> <p>22 Q Did you look at the McGwin paper?</p> <p>23 A I did not.</p> <p>24 Q Are you aware that's an epidemiological</p> <p>25 study and not a study of blood flow?</p>
Page 59	<p>1 studies that Pfizer did on Viagra?</p> <p>2 A You know, I did see that one study that</p> <p>3 they did in England, in the UK, and I read it, and I</p> <p>4 didn't -- I meant to keep -- save that article. But</p> <p>5 in the process of retiring, I simply lost that</p> <p>6 article. But it was actually a good article, and I</p> <p>7 appreciated it.</p> <p>8 Q And what's your understanding as to the</p> <p>9 conclusions from that article?</p> <p>10 A Well, it was a fairly large study, and I</p> <p>11 can't remember the exact number of people that it</p> <p>12 was done on. I would guess it was in the 300,000</p> <p>13 number of patients. But you would know probably</p> <p>14 better. But in that article, they said there was no</p> <p>15 relation -- no difference between people taking</p> <p>16 Viagra and those not taking Viagra as to the</p> <p>17 incidence of NAION.</p> <p>18 Q Have you looked at any other</p> <p>19 epidemiological studies that have been published</p> <p>20 regarding Viagra and NAION?</p> <p>21 A I've seen others, but, you know, I never</p> <p>22 did save them. I just -- these are the only ones I</p> <p>23 did save.</p> <p>24 Q Have you looked at any of the studies</p> <p>25 measuring blood flow to the optic nerve after</p>	Page 61	<p>1 A I obviously don't know that because I</p> <p>2 didn't look at it.</p> <p>3 Q Have you looked at any studies that show</p> <p>4 that Viagra does, in fact, have an effect on nitric</p> <p>5 oxide?</p> <p>6 A Just this article.</p> <p>7 Q And have you looked at any of the studies</p> <p>8 that actually did look at blood flow to the optic</p> <p>9 nerve -- or to the eye following use of Viagra?</p> <p>10 A No. Just this article is the only -- this</p> <p>11 is the only article that I have that references</p> <p>12 that.</p> <p>13 Q So you haven't looked at any of the</p> <p>14 articles that report that Viagra has no effect or,</p> <p>15 in fact, increases blood flow to the eye?</p> <p>16 A No. I haven't seen any studies that show</p> <p>17 that.</p> <p>18 Q Would those studies be relevant to your</p> <p>19 opinion?</p> <p>20 A Yes, they would.</p> <p>21 Q And if, in fact, they showed that Viagra</p> <p>22 either had no effect or increased blood flow to the</p> <p>23 eye, how would that affect your opinion?</p> <p>24 A It's still an open -- it's an open study</p> <p>25 because -- it still wouldn't -- I don't think it</p>

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Gerald McEllistrem, M.D. 10/7/2008
In Re: Viagra Products Liability Litigation

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<p>1 would change my opinion because of the clinical 2 studies, the case reports that -- this one 3 particular case report is pretty striking. And 4 there have been other case reports of blindness 5 after -- of challenge and dechallenge with Viagra 6 causing -- or being associated with blindness or 7 visual defects. 8 Q What case report are you referring to that 9 is a challenge/rechallenge associated with Viagra? 10 A Well, I think it's reported -- this is the 11 one study in -- the Pomeranz study is one case of 12 challenge. 13 Q Where is that? Which article? 14 A The study we described, you know, where 15 they rechallenge the patient with Cialis. 16 Q With Cialis? 17 A Oh, okay. Correct. And then, let's see. 18 It's in here somewhere, I just -- (Searching 19 articles.) -- I did read it in one of these 20 articles, but I'm not finding it right at the 21 moment. 22 Q You read in one of the articles about a 23 challenge/rechallenge involving Viagra? Is that 24 what you're saying? 25 A "The remaining 43 cases do not include</p>	<p>1 Q But not as a challenge/rechallenge, 2 correct? 3 A Let's see. "Forty-one patients recovered 4 with sequelae (positive dechallenge) indicating that 5 NAION improved when sildenafil therapy was 6 discontinued." That's up above the -- 7 Q Right. That's not a rechallenge though, 8 correct? 9 A Positive dechallenge. That's true. 10 That's dechallenge. 11 Q And, in fact, those cases do not appear to 12 be -- strike that. 13 Just for the record, we've marked as 14 Exhibit 5 a collection of five articles that 15 Dr. McEllistrem has provided us with today. And 16 that includes Dr. Fraunfelder, et al., Nonarteritic 17 Anterior Ischemic Optic Neuropathy and Sildenafil; 18 archives of Ophthalmology, May 2006; Akash, et al., 19 Case report: Association of combined nonarteritic 20 anterior ischemic optic neuropathy, NAION; an 21 obstruction of cilioretinal artery with overdose of 22 Viagra, Journal of Ocular Pharmacology and 23 Therapeutics 2005; Sidney Wolfe, There have been 24 inadequate warnings that erectile dysfunction drugs 25 can cause blindness, which is not a published</p>
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<p>1 information on dechallenge or rechallenge. From 2 available data, it appears that NAION was reported 3 after both single (one-time) and multiple doses of 4 sildenafil." That was in the first article -- first 5 article by Fraunfelder. 6 Q Right. But that article does not report 7 any challenge/rechallenge case on sildenafil, 8 correct? 9 A That's true. 10 Q And sildenafil is the chemical name for 11 Viagra, right? 12 A That's correct. 13 Q Do you have any of the articles that you 14 have -- let's mark this as an exhibit if we can. 15 A Sure. 16 (Deposition Exhibit Number 5 was 17 Marked for identification and is 18 Attached herewith.) 19 BY MS. LESKIN: 20 Q We've marked as Exhibit 5 the collection 21 of articles that you've provided us with today which 22 are -- 23 A The article does say that "NAION was 24 reported after both single and multiple doses of 25 sildenafil."</p>	<p>1 article, correct? 2 A That's correct. 3 Q Viagra, surgery, and anesthesia, a 4 dangerous cocktail with a risk of blindness, 5 V. Fodale, et al., Medical hypotheses 2007; an 6 excerpt from Microdex, Drugdex, 2006. Right? Those 7 are the five articles you provided? 8 A Those are the ones, yes. 9 Q Have you conducted any clinical placebo 10 controlled studies on Viagra and ischemic optic 11 neuropathy? 12 A I have not. 13 Q Have you reviewed any placebo controlled 14 studies looking at Viagra and ischemic optic 15 neuropathy? 16 A Well, the one that was produced by Pfizer 17 from the UK. 18 (Deposition Exhibit Number 6 was 19 Marked for identification and is 20 Attached herewith.) 21 BY MS. LESKIN: 22 Q Marking as Exhibit 6 an article entitled 23 Gorkin, et al., Sildenafil Citrate Use and the 24 Incidence of Nonarteritic Anterior Ischemic Optic 25 Neuropathy 2006. Is this the article you're</p>

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<p>1 referring to?</p> <p>2 A This must be the -- based on a clinical</p> <p>3 trial dated more than 13,000 men and on more than</p> <p>4 30,000 patient years of observation. This looks</p> <p>5 like the study.</p> <p>6 Q Okay. And is the conclusion reached by</p> <p>7 this analysis, reading from the summary at the top</p> <p>8 of the page, is that the data cited herein do not</p> <p>9 suggest an increased incidence of NAION in patients</p> <p>10 who took sildenafil for a day, correct?</p> <p>11 A That's correct.</p> <p>12 Q Are there any other epidemiological</p> <p>13 studies that you've reviewed?</p> <p>14 A No, there are none.</p> <p>15 (Deposition Exhibit Number 7 was</p> <p>16 Marked for identification and is</p> <p>17 Attached herewith.)</p> <p>18 BY MS. LESKIN:</p> <p>19 Q We've marked as Exhibit 7 an article by</p> <p>20 Dr. McGwin, et al., entitled Nonarteritic Anterior</p> <p>21 Ischemic Optic Neuropathy and the Treatment of</p> <p>22 Erectile Dysfunction from the British Journal of</p> <p>23 Ophthalmology 2006. And that was referred to</p> <p>24 earlier as one of the footnotes in the article you</p> <p>25 referred us to, right?</p>	<p>1 might damage the optic nerve is not as well</p> <p>2 understood. It has been theorized that sildenafil,</p> <p>3 which works through the nitric oxide-cyclic GMP</p> <p>4 pathway, may alter the perfusion of the optic nerve</p> <p>5 head by modifying nitric oxide levels."</p> <p>6 A Yes, I see that. And it also gives</p> <p>7 reference to another article by Pomeranz --</p> <p>8 Q Right.</p> <p>9 A -- in the Journal of Ophthalmology in</p> <p>10 2002.</p> <p>11 Q Right. But McGwin doesn't, in fact, do</p> <p>12 any research as to whether Viagra has an effect on</p> <p>13 the nitric oxide-cyclic GMP pathway or perfusion to</p> <p>14 the optic nerve.</p> <p>15 MR. GOMEZ: Objection to form.</p> <p>16 BY MS. LESKIN:</p> <p>17 Q Is that fair to say?</p> <p>18 A Well, it's not obvious in this article, at</p> <p>19 least if we were to look at this article.</p> <p>20 Q Have you done any research as to whether</p> <p>21 Viagra affects perfusion to the optic nerve?</p> <p>22 A No, I have not.</p> <p>23 Q Have you done any research as to whether</p> <p>24 Viagra affects nitric oxide levels in the optic</p> <p>25 nerve?</p>
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<p>1 A All true.</p> <p>2 Q And you'll see this is an epidemiological</p> <p>3 case control study, correct?</p> <p>4 A It's a retrospective case control study.</p> <p>5 Yes.</p> <p>6 Q And if you look at the results paragraph,</p> <p>7 it says, overall, males with NAION were no more</p> <p>8 likely to report a history of Viagra or Cialis use</p> <p>9 compared to similarly aged controls. Do you see</p> <p>10 that?</p> <p>11 A I see that.</p> <p>12 Q Even though it does report a statistically</p> <p>13 significant association for men with a history of</p> <p>14 myocardial infarction and an association for men</p> <p>15 with a history of hypertension that lacks</p> <p>16 statistical significance?</p> <p>17 MR. GOMEZ: Objection to form.</p> <p>18 BY MS. LESKIN:</p> <p>19 Q Right? That's what the author reports?</p> <p>20 A Yeah, I see that -- yeah, I do see that.</p> <p>21 Q And if you look at the left column on that</p> <p>22 first page, that middle paragraph --</p> <p>23 A Uh-huh.</p> <p>24 Q -- about halfway through, it says,</p> <p>25 "However, the mechanism by which these medications</p>	<p>1 A No, I have not.</p> <p>2 Q Have you read any studies that</p> <p>3 specifically look at the effect of Viagra on the</p> <p>4 nitric oxide levels in the optic nerve?</p> <p>5 A No, I have not. None others than these</p> <p>6 presented.</p> <p>7 Q Okay.</p> <p>8 (Deposition Exhibit Number 8 was</p> <p>9 Marked for identification and is</p> <p>10 Attached herewith.)</p> <p>11 BY MS. LESKIN:</p> <p>12 Q We've marked as Exhibit 8 a copy of the</p> <p>13 Viagra label. If you look at the last page, you'll</p> <p>14 see that says as of October 2007.</p> <p>15 A Let's see. October 2007, yeah.</p> <p>16 Q Okay. Earlier, we looked at the label</p> <p>17 from 1999 that discussed reports of heart attack,</p> <p>18 correct?</p> <p>19 A We saw that, right. Yes, I did see that.</p> <p>20 Q And if you look at page 21 of Exhibit 8,</p> <p>21 you'll see that same paragraph again regarding</p> <p>22 cardiovascular events reported in connection with</p> <p>23 Viagra, right?</p> <p>24 A I see that, uh-huh.</p> <p>25 Q If you turn the page, you'll see in the</p>

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<p>1 middle of the page there under "Special Senses,"</p> <p>2 there's a paragraph that reads, "Non-arteritic</p> <p>3 anterior ischemic optic neuropathy (NAION), a cause</p> <p>4 of decreased vision including permanent loss of</p> <p>5 vision, has been reported rarely post-marketing in</p> <p>6 temporal association with the use phosphodiesterase</p> <p>7 Type 5 (PDE5) inhibitors, including VIAGRA. Most,</p> <p>8 but not all, of these patients had underlying</p> <p>9 anatomic or vascular risk factors for developing</p> <p>10 NAION, including but not necessarily limited to:</p> <p>11 low cup to disc ratio ("crowded disc"), age over 50,</p> <p>12 diabetes, hypertension, coronary artery disease,</p> <p>13 hyperlipidemia and smoking. It is not possible to</p> <p>14 determine whether these events are related directly</p> <p>15 to the use of PDE5 inhibitors, to the patient's</p> <p>16 underlying vascular risk factors or anatomical</p> <p>17 defects, to a combination of these factors, or to</p> <p>18 other factors." Do you see that paragraph?</p> <p>19 A I do see that paragraph.</p> <p>20 Q And that's a true statement, correct?</p> <p>21 A That's correct.</p> <p>22 Q And you would agree with that paragraph?</p> <p>23 A I would agree.</p> <p>24 MS. LESKIN: I have nothing further.</p> <p>25 EXAMINATION</p>	<p>1 Q My question to you is this -- well, strike</p> <p>2 that.</p> <p>3 It's my understanding that some patients</p> <p>4 when told that decide not to take the drug, correct?</p> <p>5 A That's true.</p> <p>6 Q Are you sure the time frame of the year</p> <p>7 2000, or is that a speculation on your part?</p> <p>8 A That's speculation.</p> <p>9 MS. LESKIN: Objection.</p> <p>10 MR. GOMEZ: I just want to take a look at</p> <p>11 my notes, Doctor. I don't want to take much</p> <p>12 more of your time.</p> <p>13 Doctor, that's all the questions I have.</p> <p>14 THE WITNESS: Okay.</p> <p>15 MS. LESKIN: I just have one other</p> <p>16 question for you.</p> <p>17 EXAMINATION</p> <p>18 BY MS. LESKIN:</p> <p>19 Q You're not an ophthalmologist, correct?</p> <p>20 A That's correct.</p> <p>21 Q And you're not a neuro-ophthalmologist?</p> <p>22 A That's correct.</p> <p>23 Q Is it fair to say that the treatment and</p> <p>24 diagnosis of eye problems is not your area of</p> <p>25 specialty?</p>
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<p>1 BY MR. GOMEZ:</p> <p>2 Q Doctor, you would agree with me that there</p> <p>3 could -- strike that.</p> <p>4 Let me introduce myself. My name is Chris</p> <p>5 Gomez. I'm here on behalf of Mr. Martin.</p> <p>6 Just so I'm clear and the jury</p> <p>7 understands, there can be more than one cause for a</p> <p>8 medical event. Do you agree with that?</p> <p>9 A I do.</p> <p>10 Q Now, after -- it's my understanding that</p> <p>11 you gave an opinion to a reasonable degree of</p> <p>12 medical certainty that Mr. Martin's ingestion of</p> <p>13 Viagra was a cause, not the cause, but a cause of</p> <p>14 his NAION, correct?</p> <p>15 A That's correct.</p> <p>16 Q And after all the articles that Ms. Leskin</p> <p>17 showed you, you still keep that opinion, correct?</p> <p>18 A I do.</p> <p>19 Q I want to just back up a little bit.</p> <p>20 Earlier on in your testimony, you talked about when</p> <p>21 you -- back in 2000, you talked about prescribing --</p> <p>22 or talking about the risk factors of Viagra</p> <p>23 including potential blindness with your patients.</p> <p>24 Do you remember talking about that?</p> <p>25 A Yes. I remember that.</p>	<p>1 A That's true.</p> <p>2 Q And you would defer to an ophthalmologist</p> <p>3 to treat and care for someone's visual problems?</p> <p>4 A Yes, I would.</p> <p>5 Q And you would defer to a</p> <p>6 neuro-ophthalmologist or an ophthalmologist to</p> <p>7 diagnose a person's visual problems?</p> <p>8 A I would.</p> <p>9 MS. LESKIN: Thank you.</p> <p>10 MS. MCELLISTREM: Read and sign.</p> <p>11 MS. LESKIN: Thank you very much.</p> <p>12 THE WITNESS: Thank you.</p> <p>13 (Deposition concluded at 10:29 p.m.)</p> <p>14 *****</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>

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REPORTER'S CERTIFICATE

STATE OF MINNESOTA)

) ss.

COUNTY OF HENNEPIN)

I hereby certify that I reported the deposition of GERALD MCELLISTREM, M.D., on the 7th day of October, 2008, in Minneapolis, Minnesota, and that the witness was by me first duly sworn to tell the whole truth;

That the testimony was transcribed by me and is a true record of the testimony of the witness;

That the cost of the original has been charged to the party who noticed the deposition, and that all parties who ordered copies have been charged at the same rate for such copies;

That I am not a relative or employee or attorney or counsel of any of the parties, or a relative or employee of such attorney or counsel;

That I am not financially interested in the action and have no contract with the parties, attorneys, or persons with an interest in the action that affects or has a substantial tendency to affect my impartiality;

That the right to read and sign the deposition by the witness was reserved.

WITNESS MY HAND AND SEAL, this 22nd day of October, 2008.

Lori L. Morrow, RPR, CRR, CLR
Notary Public, Hennepin County, Minnesota
My commission expires: January 31, 2010

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